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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,724	09/25/2003	W. Edward Robinson JR.	UCIVN-040C	8496

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MEDLEN & CARROLL, LLP
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EXAMINER

HUYNH, CARLIC K

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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05/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/672,724	ROBINSON ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-32 is/are pending in the application.
- 4a) Of the above claim(s) 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>28 August 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 24-38 are pending in the application, with claims 24-27 and 33-38 having been cancelled, in response to the restriction requirement submitted on December 14, 2006.

Accordingly, claims 28-32 are being examined on the merits herein.

Election/Restrictions

2. Applicant's cancellation of claims 24-27 and 33-38 in the reply filed on February 23, 2007 is acknowledged.

Applicant's election without traverse of Group II, namely claims 28-32, in the reply filed on February 23, 2007 is acknowledged.

Applicant's election without traverse of the species of (1) zidovudine as a species of a reverse transcriptase inhibitor and (3) L-Chicoric acid as a species of an integrase inhibitor, in the reply filed on February 23, 2007 is acknowledged.

Claim 28 is read to draw on the elected species of L-Chicoric acid.

Claims 29-30 are read to draw on the elected species of zidovudine.

Claims 31-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on February 23, 2007.

The restriction requirement and the election of species requirement of (1) zidovudine as a species of a reverse transcriptase inhibitor and (3) L-Chicoric acid as a species of an integrase inhibitor are still deemed proper and are therefore made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on August 28, 2006 is acknowledged.

Drawings

3. The drawings are objected to because of “μ” in figure 3b. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The use of the trademark Lipofectin, Purescript, Superscript II, PCRScript, Sequenase II, and Viracept has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Clercq (Reviews in Medical Virology, Jul/Aug 2000, vol. 10, no. 6, pages 255-277).

De Clercq teaches combination therapy for HIV-infected patients, comprising at least 3 anti-HIV drugs from the following groups: (1) nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs); (2) non-nucleoside reverse transcriptase inhibitors (NNRTIs); (3) protease inhibitors; and (4) integrase inhibitors (abstract and page 1). Such compounds include zidovudine, a reverse transcriptase inhibitor, and L-chicoric acid, an integrase inhibitor (pages 263 and 266, respectively). De Clercq also teaches that a NNRTI, UC-781, has been able to

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restore the anti-viral activity of AZT, a common reverse transcriptase inhibitor, against AZT-resistant HIV (page 265).

Since De Clerq teaches therapy comprises of at least 3 compounds and a NNRTI, UC-781, can be used to treat AZT-resistant HIV, it would be obvious to one skilled in the art to use L-chicoric acid along with zidovudine and UC-781 to treat reverse transcriptase-resistant HIV.

6. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beale et al. (Antiviral Research, June 1, 2000, vol. 46, pages 223-232).

Beale et al. teach combination therapy of L-chicoric acid (an integrase inhibitor) with zidovudine (a reverse transcriptase inhibitor) in reverse transcriptase-resistant strains of HIV-1 (abstract).

Beale et al. do not teach administration of L-chicoric acid and zidovudine to human patients. However, Beale et al. teaches that L-chicoric acid and zidovudine have been approved by the FDA for use in HIV-infected individuals (page 230). Since L-chicoric acid and zidovudine have been FDA approved for use in HIV-infected individuals, it would have been obvious to one skilled in the art to administer such compounds to humans.

Conclusion

7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

SHENG NIN WANG
PRIMARY EXAMINER